

FOR UTILITY/DESIGN
CIP/PCT NATIONAL/PLANT
ORIGINAL/SUBSTITUTE/SUPPLEMENTAL
DECLARATIONS

RULE 63 (37 C.F.R. 1.63)
DECLARATION AND POWER OF ATTORNEY
FOR PATENT APPLICATION
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

P3103 (C) /US
CUSHMAN
FORM

As a below named inventor, I hereby declare that my residence, post office address and citizenship are as stated below next to my name, and I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the INVENTION ENTITLED: TEST METHODS, DEVICES AND TEST KITS

the specification of which (CHECK applicable BOX(ES))
-> [] is attached hereto
X -> [X] was filed on April 2, 1999 as U.S. Application No. _____ not yet known
Box(es) -> [] was filed as PCT International Application No. PCT/ _____ on _____
-> and (if applicable to U.S. or PCT application) was amended on _____

JUL 0 1 1999
PATENT & TRADEMARK OFFICE

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose all information known to me to be material to patentability as defined in 37 C.F.R. 1.56. I hereby claim foreign priority benefits under 25 U.S.C. 119/365 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate filed by me or my assignee disclosing the subject matter claimed in this application and having a filing date (1) before that of the application on which priority is claimed, or (2) if no priority claimed, before the filing date of this application:

| PRIOR FOREIGN APPLICATION(S) | | Date First Laid - open or Published | Date Patented or granted | Priority Claimed Yes No |
|------------------------------|----------------|--|-----------------------------|----------------------------|
| Number | Country | Day/MONTH/Year Filed | | |
| 9807134.3 | UNITED KINGDOM | 2 APRIL 1998 | | YES |

I hereby claim domestic priority benefit under 35 U.S.C. 120/365 of the indicated United States applications listed below and PCT international applications listed above or below and, if this is a continuation-in-part (CIP) application, insofar as the subject matter disclosed and claimed in this application is in addition to that disclosed in such prior applications, I acknowledge the duty to disclose all information known to me to be material to patentability as defined in 37 C.F.R. 1.56 which became available between the filing date of each such prior application and the national or PCT international filing date of this application:

| PRIOR U.S. PROVISIONAL, NONPROVISIONAL AND/OR PCT APPLICATION(S) | | Status | Priority Claimed Yes No |
|--|----------------------|------------------------------|----------------------------|
| Application Number (series code/serial no.) | Day/MONTH/Year Filed | pending, abandoned, patented | |

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

And I hereby appoint Cushman Darby & Cushman Intellectual Property Group of Pillsbury Madison & Sutro L.L.P. 1100 New York Avenue, N.W., Ninth Floor, East Tower, Washington D.C. 20005-3918, telephone number (202) 861-3000 (to whom all communications are to be directed), and the below-named persons (of the same address) individually and collectively my attorneys to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith and with the resulting patent, and I hereby authorize them to delete names/numbers below of persons no longer with their firm and to act and rely on instructions from and communicate directly with the person/assignee/attorney/firm/organization who/which first sends/sent this case to them and by whom/which I hereby declare that I have consented after full disclosure to be represented unless/until I instruct the above Firm and/or a below attorney in writing to the contrary.

| | | | |
|----------------------------|---------------------------|----------------------------|--------------------------|
| Paul N. Kokulis 16773 | David W. Brinkman 20817 | Chris Comuntzis 31097 | James D. Berquist 34776 |
| Raymond F. Lippitt 17519 | George M. Sirilla 18221 | Paul E. White Jr. 32011 | Timothy J. Klima 34852 |
| G. Lloyd Knight 17698 | Donald J. Bird 25323 | Michelle N. Lester 32331 | John P. Moran 30906 |
| Carl G. Love 18781 | W. Warren Taltavull 25647 | Jeffrey A. Simenauer 31993 | Stephen C. Glazier 31361 |
| Edgar H. Martin 20534 | Peter W. Gowdey 25872 | G. Paul Edgell 24238 | Paul F. McQuade 31542 |
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| Kevin E. Joyce 20508 | Glenn J. Perry 28458 | David A. Jakopin 32995 | |
| Edward M. Prince 22429 | Kendrew H. Colton 30368 | Mark G. Paulson 30793 | |

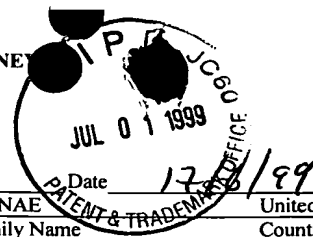
1) INVENTOR'S SIGNATURE: Michael Catt Date 10/5/99
Inventor's Name (typed) Michael CATT United Kingdom
First Middle Initial Family Name Country of Citizenship
Residence (City) Bedford (State/Foreign Country) United Kingdom
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2) INVENTOR'S SIGNATURE: Rosie Habeshaw Date 10/5/99
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3) INVENTOR'S SIGNATURE: Keith May Date 10/5/99
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First Middle Initial Family Name Country of Citizenship
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(FOR ADDITIONAL INVENTORS, check box [] and attach sheet CDC-116.2 for same information for each re signature, name, date, citizenship, residence and address CDC-1

DECLARATION AND POWER OF ATTORNEY
(Continued)
ADDITIONAL INVENTORS



- 4) INVENTOR'S SIGNATURE: [Signature] Date 17/06/99
Inventor's Name (typed) Fiona MCNAE United Kingdom
First Middle Initial Family Name Country of Citizenship
Residence (City) London (State/Foreign Country) United Kingdom
Post Office Address (Include Zip Code) Ground Floor Flat, 16B Oswald Road, London SW17 7SS, United Kingdom
- 5) INVENTOR'S SIGNATURE: [Signature] Date 10th May 1999
Inventor's Name (typed) Andrew P PHELAN United Kingdom
First Middle Initial Family Name Country of Citizenship
Residence (City) Bedford (State/Foreign Country)
Post Office Address (Include Zip Code) c/o Unipath Ltd, Priory Business Park, Bedford, MK44 3UP, United Kingdom
- 6) INVENTOR'S SIGNATURE: _____ Date _____
Inventor's Name (typed) _____
First Middle Initial Family Name Country of Citizenship
Residence (City) _____ (State/Foreign Country)
Post Office Address (Include Zip Code) _____
- 7) INVENTOR'S SIGNATURE: _____ Date _____
Inventor's Name (typed) _____
First Middle Initial Family Name Country of Citizenship
Residence (City) _____ (State/Foreign Country)
Post Office Address (Include Zip Code) _____
- 8) INVENTOR'S SIGNATURE: _____ Date _____
Inventor's Name (typed) _____
First Middle Initial Family Name Country of Citizenship
Residence (City) _____ (State/Foreign Country)
Post Office Address (Include Zip Code) _____
- 9) INVENTOR'S SIGNATURE: _____ Date _____
Inventor's Name (typed) _____
First Middle Initial Family Name Country of Citizenship
Residence (City) _____ (State/Foreign Country)
Post Office Address (Include Zip Code) _____
- 10) INVENTOR'S SIGNATURE: _____ Date _____
Inventor's Name (typed) _____
First Middle Initial Family Name Country of Citizenship
Residence (City) _____ (State/Foreign Country)
Post Office Address (Include Zip Code) _____

Rule (a) & (b) = 37 C.F.R. 1.56(a) &
PATENT AND TRADEMARK CASES - RULES OF PRACTICE
DUTY OF DISCLOSURE

- (a) ...Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the [Patent and Trademark] Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability ... (b) information is material to patentability when it is not cumulative and (1) It also establishes by itself, or in combination with other information, a prima facie case of unpatentability of a claim or (2) refers, or is inconsistent with, a position the applicant takes in: (i) Opposing an argument of unpatentability relied on by the Office, or (ii) Asserting an argument of patentability.

PATENT LAWS 35 U.S.C.



§102. Conditions for patentability; novelty and loss of right to patent

A person shall be entitled to a patent unless--

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent or
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or
- (c) he has abandoned the invention, or
- (d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months* before the filing of the application in the United States, or
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent, or
- (f) he did not himself invent the subject matter sought to be patented, or
- (g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

§103. Conditions for patentability; non-obvious subject matter

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made. Subject matter developed by another person, which qualified as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

* Six months for Design Applications (35 U.S.C. 172).